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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/098,625	03/18/2002	Gunnar Fager	3764-120	3908
23117	7590	03/09/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			KIM, SUN U	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/098,625

Applicant(s)

FAGER, GUNNAR

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 12-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/508,766.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/30/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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1. Information disclosure statement filed on 12/30/03 has been considered by the examiner.
2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. For instance, the specification needs to specify that "this application is a continuation of application no. 09/508,766 filed 3/16/00, abandoned, which is a 371 of PCT/SE00/00030 filed 1/11/00 which claims the benefit to Sweden patent application no. 9900043-2 filed 1/11/99."
3. Claims 12-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over English translated copy of French Patent No. 2,687,070 (hereinafter referred to as FR '070) in view of WO94/29366 or WO97/30073 and WO97/39770. FR '070 teaches a dialysis concentrate containing low molecular weight heparin obtained by fragmenting the standard heparin as an anticoagulant wherein dialysis solution is made from the concentrate used in hemodialysis process (see page 1, lines 1-4; page 2, line 1 – page 5, line 15). FR '070 further teaches that "The lighter molecular weights of these fragments therefore enable them to cross the membranes which are currently employed in haemodialysis and thus permit spontaneous fractionation of the standard heparin, if the latter is present in the dialysate. Other anticoagulatory agents can be used in the dialysis bath if their molecular weights enable them to cross the membranes employed in haemodialysis sessions. Precursors of anticoagulatory agents may be added to the concentrated solutions provided that their reaction with other compounds present in the dialysate

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leads to the formation of an anticoagulatory agent.” (see page 3, lines 4-16). Claims 12-41 essentially differ from FR ‘070 in reciting the low molecular weight thrombin inhibitor including inogatran or melagatran in dialysis solution or concentrate. WO94/29366 teaches the use of a low molecular weight thrombin inhibitor including melagatran as anticoagulant in hemodialysis process and formed in a pharmaceutically acceptable dosage form in a form of a solid, semisolid or liquid preparation (see pages 43-46). WO97/30073 teaches the use of a low molecular weight thrombin inhibitor including inogatran like thrombin inhibitor as anticoagulant in hemodialysis process and formed in a pharmaceutically acceptable dosage in a form of a solid, semisolid or liquid preparation (see pages 1-3, 9). WO97/39770 teaches that low molecular weight thrombin inhibitors including melagatran and inogatran, acting as anticoagulants, rapidly clears from the body (see page 1, lines 6-17). It would have been obvious to a person of ordinary skill in the art to substitute low molecular weight thrombin inhibitor including melagatran and inogatran as anticoagulants for low molecular weight anticoagulatory agents in the dialysis concentrate of FR ‘070 in order to take advantage of rapid clearing of anticoagulants from the body after the hemodialysis treatment.

4. The declaration under 37 CFR 1.132 filed 12/30/03 is insufficient to overcome the rejection of claims 12-41 based upon FR ‘070 in view of WO94/29366 or WO97/30073 and WO97/39770 as set forth in the last Office action because: FR ‘070 suggests the use of other anticoagulatory agents in the dialysis bath if their molecular weights enable them to cross the membranes employed in hemodialysis sessions and such low molecular weight anticoagulants are taught in WO94/29366 or WO97/30073 and WO97/39770.

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5. Applicant's arguments with respect to claims 12-41 have been considered but are moot in view of the new ground(s) of rejection.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for official response is (703) 872-9306.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.



**John Kim**  
**Primary Examiner**  
**Art Unit 1723**

J. Kim  
March 3, 2004